

## Health and Human Services (HHS) STTR Quick-Start Guide

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This quick-start guide has been designed to get you started with a HHS STTR proposal package.

HHS posts their general solicitation as an [Omnibus](#), either for [Clinical Trial Required](#) or [Clinical Trial Not Allowed](#) projects, or as [Targeted Solicitations](#). They also release [Contracts](#). Viewing these will give you a brief overview of the general requirements for a HHS STTR package. HHS also separates their [Research Topics](#) out into a different document. It can be difficult to figure out what topic and type of submission you need, so please reach out to NM FAST staff if you need assistance in this area.

For HHS, you will need the following registrations. It is important that you complete these registrations as soon as possible, as some can take up to 14 days to issue, and not having these in place can impact your ability to submit a proposal. Please reach out to the NM FAST team if you need assistance with any of these registrations. Additionally, the New Mexico APEX Accelerators can assist you in the SAM registration processes, including securing a Unique Entity Identifier (UEI). You can contact one of their offices to receive one-on-one help. A list of New Mexico APEX Accelerators offices can be found at the bottom of their [Contact Us](#) page.

1. **SAM:** The System for Award Management, or SAM, is the first registration to complete in terms of priority. There are a few steps to getting your SAM registration in place. The first one is that you must create a Login.gov account, which you will be prompted to do when you click the registration link below. If you have never registered your business, you will also create a Unique Entity Identifier (UEI) during this process; if you have already registered with the government, you will be able to transition your DUNS into a UEI, or it is already available to you in a SAM registration. While the digital portion of this registration can take up to an hour, as it requires quite a few markers for your business, including your foundation date, points of contact (which can all be the same person), and your ACH banking information, the information you input will go through a series of government checks. It is not unheard for it to be a four to six week process. Please plan accordingly. <https://sam.gov/content/entity-registration>. The following video walks you through this process: <https://www.youtube.com/watch?v=0uv1YNAsINk>
2. **SBC Control ID:** This registration is required by the Small Business Administration (SBA), which coordinates the SBIR/STTR programs. You have to have your UEI, at minimum, to complete this registration. <https://www.sbir.gov/registration>
3. **Grants.gov:** This is the submission site for HHS. It will require you to have completed your UEI and SAM. <https://www.sbir.gov/registration>
4. **eRA Commons:** This is the management portal for HHS grants/contracts. All documentation related to your award will flow through this vehicle. <https://www.grants.gov/>. Additionally, in situations where the PD/PI is primarily employed by the Research Institution, the PD/PI must be affiliated with the applicant SBC submitting the application and will serve as the Contact PD/PI. The Contact PD/PI may be from either the SBC or the single partnering research institution.

Though HHS does not require an Executive Summary to be submitted for idea validation, it is a good idea to reach out to a cognizant Program Manager for idea validation before starting your proposal narrative. When performing a topic match, NM FAST staff can put you in touch with the most relevant HHS Program Manager to discuss the fit of your innovative idea.

The following are some action items and next steps for you to complete as you start your SBIR package.

1. **Budget** – Depending on the HHS agency, Phase I awards fund up to \$275,766 over a period of 6 to 24 months for a feasibility study. The feasibility study will typically include researching the proposed methodology, laboratory testing and environment replication if necessary, and any other markers to verify that your idea has merit for prototype production (Phase II). As you know the tentative scope of the work and the budget threshold, it is a good idea to start formulating some costs and making decisions on materials and equipment needs (if available).
2. **Collaboration** – If you have not already secured a relationship with a Research Institution (a requirement of the STTR program), then you will want to start performing your outreach before sketching any action items or work plans. If you have already established a working relationship with a RI, it is a good idea to start formulating a work plan and action items for the intended project. Additionally, as budgetary compliance issues, statements of work, and signed letters of commitment are necessary components, and might take a long time to authorize through your partner organization, you will want to start requesting those items at your first convenience.
3. **Required Forms** – Though we will send you a compliance matrix that lays out all of the necessary formatting requirements, sections, and content for your proposal, it is a good idea to familiarize yourself with the information that needs to populate those sections, as well as begin any necessary research.
  - a. **Biographical Sketch** – All senior/key personnel and other significant contributors (OSCs) must include biographical sketches (biosketches). Follow the template found [here](#).
  - b. **Facilities and Other Resources and Equipment Documentation** – These two documents will specify the availability and location of significant equipment, instrumentation, computers, and physical facilities necessary to complete the project and the manner in which the small business has access to these items. This is also a place to report equipment you have (teleconferencing, office computers, etc.) that will assist in communicating with project stakeholders.

The NM FAST team has a suite of resources (e.g. [YouTube](#) instructional videos, check-lists, compliance matrices, etc.) available for use in proposal creation. Please reach out to Milica Tenic ([tenic@nmsu.edu](mailto:tenic@nmsu.edu)) for more information.